

Remarks

A. Pending Claims

Claims 29, 31, 33-34, 38, 42, 45, 46, 48-54, 56, 60 and 61 have been rejected. Claims 29 and 56, 60 and 61 have been amended. Claims 62-67 have been added. Claims 29, 31, 33-34, 38, 42, 45-46, 48-54, 56, 60-67 are pending.

B. The Claims Are Not Anticipated By Heyn Pursuant To 35 U.S.C. § 102(b)

Claims 29, 42, 45-46, 48-51, 54, 56 and 60-61 were rejected pursuant to 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,201,757 to Heyn et al. ("Heyn"). Applicant respectfully submits that the claims are allowable for at least the following reasons.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); *In re Donahue*, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Further, the Examiner must consider all words in a claim in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970); M.P.E.P. §2143.03. (Emphasis added). When evaluating the scope of a claim, every limitation in the claim must be considered. A claimed invention may not be dissected into discrete elements and then the elements reevaluated in isolation. Instead, the claim as a whole must be considered. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 188-89, 209 USPQ 1, 9 (1981)

Independent Claim 29

Amended claim 29 recites a combination of features including, but not limited to:

a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent on or between distal

portions of the first and the second conduits, wherein the stent comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end, wherein the second conduit is movably positionable with respect to the first conduit, and wherein a distal end of the second conduit is movable in a direction toward a proximal end of the first conduit to expose at least a portion of the distal end of the stent contained between the distal portions of the first and second conduits during use.

With respect to the claims, the Office Action states:

Heyn discloses a first conduit 44, wherein at least a portion of an endoscope or bronchoscope, having at least a portion that is partially flexible, may be positionable in the first conduit during use, ... and a second conduit 20, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent 18 between the distal ends of the first and second conduits, and wherein the second conduit is configurable to releasably position the stent in a body lumen or air passage during use (Figure 1, col. 5, lines 15-23). The distal end of the second conduit 20 is configured to expose the stent 18 upon retracting proximally (col. 6, lines 23-27).
(Office Action, page 3)

Applicant respectfully disagrees with the Office Action's position that Heyn teaches all of the features of claim 29. Applicant respectfully submits that the cited art does not appear to teach or suggest at least the above-cited combination of features.

Heyn discloses:

An apparatus for deploying a radially self-expanding stent includes proximal and distal sleeves respectively containing proximal and distal end portions of the stent in a reduced radius delivery configuration. The sleeves can abut one another and thus contain the entire length of the stent, or may be used in combination with an outer catheter surrounding the sleeves and containing the medial region of the stent. In either event, once the stent and sleeves are positioned at the intended fixation site, the sleeves are moved axially with respect to one another to permit radial self-expansion of the stent only over its medial region, while the sleeves continue to contain the axially outward regions of the stent. Eventually, upon sufficient movement of the sleeves axially relative to one another, the stent becomes totally free of the sleeves, resulting in radial expansion

over the entire stent length. The axial relative movement of the sleeves can be controlled by two or more catheters mounted movably with respect to one another, one catheter integral with each of the sleeves. Alternative arrangements for separating the sleeves include an externally threaded inner catheter, and a dilatation balloon or membrane expandable to force the sleeves apart from one another.
(Heyn, abstract)

Heyn also discloses:

Distal movement of finger grip 60 moves distal sleeve 30 distally away from the more proximal sleeve 24, to deploy the distal portion of the stent. Either movement, or both in combination, will form a gap at interface 32 to allow limited radial expansion of stent 18, in particular near its center, while the proximal and distal regions remain confined between sleeves 24 and 30, respectively.
(Heyn, col. 6, lines 27-34)

Heyn appears to disclose an apparatus for deploying a radially self-expanding stent [that] includes proximal and distal sleeves. The sleeves are moved axially with respect to one another to permit radial self-expansion of the stent only over its medial region. For example, Heyn discloses, in FIG. 1, sleeves (24 and 30) that are coupled at an interface (32). Distal movement of the distal sleeve (30) away from the proximal sleeve (24) appears to cause a rupture of the interface (32) and forms a gap that allows limited radial expansion of the stent (18) (See Heyn, FIG. 3). It appears that the middle portion of the stent (18) expands through the gap while the ends of the proximal region (26) and the distal region (38) of the stent (18) remain confined by the sleeves (24 and 30). Accordingly, Heyn appears to disclose that proximal retraction of “distal end” of the second conduit (20) exposes a middle portion of stent (18). Heyn, however, does not appear to teach or suggest exposing at least a distal end of the stent. Heyn, thus, does not appear to teach or suggest at least the features of, “a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent on or between distal portions of the first and the second conduits, wherein the stent comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end, wherein the second conduit is movably positionable with respect to the first conduit, and wherein a distal end of the second conduit is movable in a direction toward a proximal end of the first conduit to expose at least a portion of the distal end

of the stent contained between the distal portions of the first and second conduits during use” in combination with other features of the claim.

For at least these reasons, Applicant respectfully submits that claim 29 is allowable over the cited art.

Independent Claims 56

Amended claim 56 recites a combination of features including, but not limited to:

- a first conduit, wherein at least a portion of a bronchoscope is positionable in the first conduit during use, wherein the first conduit is sized to allow an endoscope to move through the first conduit, and wherein the first conduit comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end;

- a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, and wherein the second conduit comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end; and

- a stent disposed between the distal portions of the first and second conduits, wherein the stent comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end,

- wherein the second conduit is configured to contain substantially all of the stent between the distal portions of the first and the second conduits, wherein the second conduit is movably positionable with respect to the first conduit, and wherein the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose at least a portion of the distal portion of the stent during use.

For at least reasons similar to those discussed above, Applicant respectfully submits that claim 56 is allowable over the cited art. Moreover, Applicant respectfully submits that claim 56 recites additional features that are not anticipated by the cited art. For example, claim 56 recites in part, “wherein the second conduit is configured to contain substantially all of the stent between the distal portions of the first and the second conduits.” Such a feature, in combination with other features of the claim, does not appear to be disclosed by Heyn.

Heyn discloses a distal portion (“sleeve” (24)) of a catheter (20) that surrounds a proximal region (26) of stent (18), and a distal sleeve (30) that surrounds a distal region (38) of

stent (18). Heyn, thus, appears to disclose some of the stent residing between conduits. Heyn, however, does not appear to disclose substantially all of a stent between the distal portions of first and the second conduits. Accordingly Heyn does not appear to teach or suggest at least the feature of, “wherein the second conduit is configured to contain substantially all of the stent between the distal portions of the first and the second conduits, wherein the second conduit is movably positionable with respect to the first conduit, and wherein the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose at least a portion of the distal portion of the stent during use,” in combination with other features of the claim.

For at least these reasons, Applicant respectfully submits that claim 56 is allowable over the cited art.

Independent Claims 61

Amended claim 61 recites a combination of features including, but not limited to:

a second conduit, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent on or between distal ends of the first and the second conduits, wherein the stent comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end, and wherein the second conduit is movably positionable with respect to the first conduit, and wherein the distal end of the stent is exposed prior to exposure of other portions of the stent upon movement of the second conduit in a proximal direction relative to the first conduit.

For at least reasons similar to those discussed above, Applicant respectfully submits that claim 61 is allowable over the cited art. Moreover, Applicant respectfully submits that claim 61 recites additional features that are not anticipated by the cited art. For example, claim 56 recites in part, “wherein the distal end of the stent is exposed prior to exposure of other portions of the stent upon movement of the second conduit in a proximal direction relative to the first conduit.” Such a feature, in combination with other features of the claim, does not appear to be disclosed by Heyn.

As discussed above, Heyn discloses, in FIG. 1, sleeves (24 and 30) that are coupled at an interface (32). Distal movement of the distal sleeve (30) away from the proximal sleeve (24) appears to cause a rupture of the interface (32) and forms a gap that allows limited radial expansion of the stent (18) (See Heyn, FIG. 3). It appears that the middle portion of the stent (18) initially expands through the gap while the ends of the proximal region (26) and the distal region (38) of the stent (18) remain confined by the sleeves (24 and 30). Accordingly, Heyn appears to disclose that proximal retraction of a “distal end” of the second conduit (20) exposes a middle portion of stent (18). Heyn, however, does not appear to teach or suggest exposing a distal end of the stent prior to exposing other portions of the stent. Accordingly Heyn does not appear to teach or suggest at least the feature of, “wherein the stent comprises a distal portion terminating at a distal end and a proximal portion terminating at a proximal end, and wherein the second conduit is movably positionable with respect to the first conduit, and wherein the distal end of the stent is exposed prior to exposure of other portions of the stent upon movement of the second conduit in a proximal direction relative to the first conduit,” in combination with other features of the claim.

For at least these reasons, Applicant respectfully submits that claim 61 is allowable over the cited art.

Dependent Claims

Applicant believes many of the dependent claims may be separately patentable. For example, claim 48 describes a combination of features including: “wherein at least a portion of the first conduit is configured to inhibit collapse of the first conduit upon removal of the endoscope during use.” Similarly, claim 49 describes a combination of features including: “wherein at least a portion of the second conduit is configured to inhibit collapse of the second conduit.” With respect to these claims, the Examiner states, “Heyn discloses at least a portion of the first and second conduits being configured to inhibit collapse of the first and second conduits upon removal of an endoscope during use (col. 5, lines 63-67 to col. 6, lines 1-5).” (Office Action, page 3). The cited portion of Heyn appears to relate to the coefficient of friction between a stent, a sleeve and/or a catheter, presumably to enable sliding of the components relative to one another.

The cited portion of Heyn does not appear to even consider inhibiting the collapse of a first or second conduit.

In response to similar arguments previously presented, the Office Action states:

Applicant also argues that Heyn does not appear to disclose inhibiting the collapse of a first or second conduit. However, as maintained above, Heyn discloses in col. 5, line 63 to col. 6, line 5 that certain materials are selected for the sleeves or the conduits which may include a coating of Teflon, which might add rigidity to the conduits and therefore inhibit collapse.
(Office Action, page 8)

Accordingly, the Office Action appears to take the position that a Teflon coating increases rigidity and inhibits collapse. Applicant respectfully disagrees. As noted in Heyn, as well as in Applicant's specification, Teflon is a coating that is used to reduce coefficients of friction. (*See* Heyn, col. 5, lines 63-68); and (*See* Applicant's Specification, page 8, lines 1-3). Neither appears to suggest Teflon being used to increase rigidity. Thus, it appears the Office Action is suggesting that such a feature is inherent. Applicant notes that to rely on the theory of inherency, the examiner must "provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original.) Inherency may not be established by probabilities or possibilities; the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Moreover, Applicant notes that in certain circumstances an examiner may take official notice of facts not in the record or rely on "common knowledge" in making a rejection, however, such rejections should be judiciously applied. M.P.E.P. §2144.03. It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. Id.. If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. (*See* 37 CFR 1.104(d)(2)).

For at least these reasons, Applicant respectfully submits that claims 48 and 49 are allowable over the cited art.

C. The Claims Are Not Obvious Over Heyn In View of Bui Pursuant To 35 U.S.C. § 103(a)

Claim 31 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 6,629,981 to Bui et al. ("Bui"). For at least these reasons similar to those discussed above, Applicant respectfully submits that claim 31 is allowable over the cited art.

D. The Claims Are Not Obvious Over Heyn In View of Gunderson Pursuant To 35 U.S.C. § 103(a)

Claims 33-34 and 53 were rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 5,776,142 to Gunderson ("Gunderson"). Applicant respectfully disagrees.

Dependent Claims 33 and 34

Claim 33 describes a combination of features including, but not limited to, the feature of: "a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises: a first grip coupled to at least a portion of the first conduit; and a second grip coupled to at least a portion of the second conduit; wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip." Claim 34 describes a combination of features including, but not limited to, the feature of: "further comprising a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises: a first grip coupled to at least a portion of the first conduit; a second grip coupled to at least a portion of the second conduit; and one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other; wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction

toward a proximal end of the stent delivery system beyond the portion of the first grip.”

The Office Action states:

Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use...

...

Gunderson teaches a lock configurable to inhibit movement of the first conduit to the second conduit during use, wherein the lock comprises a first grip 20 coupled to at least a portion of the first conduit, and a second grip 30 coupled to at least a portion of the second conduit, and one or more pins 28 coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip (Figure 1, col. 5, lines 7-16).

(Office Action, page 5)

Applicant respectfully disagrees for at least the following reasons.

Gunderson discloses:

With the two handles 20 and 30 fixedly attached to the inner and outer sheaths 40 and 50, it will be understood that rotation of the handles 20 and 30 relative to each other will cause corresponding relative rotation between the inner and outer sheaths 40 and 50. The screw portion 26 of handle 20 and corresponding screw receiving portion 32 of handle 30, it will also be understood that relative rotation of the handles 20 and 30 will also cause relative movement along the longitudinal axis of the device between the inner and outer sheaths 40 and 50 as will be discussed in more detail below.

(Gunderson, column 5, lines 7-16).

Gunderson further discloses:

The handle 20 is preferably fixedly attached to the inner sheath 40 such that rotation of the handle 20 about the longitudinal axis of the device results in corresponding rotation of the inner sheath 40. The handle 20 also preferably includes a screw portion 26 including threads 28 as shown in FIG. 1.

The second handle 30 preferably includes a threaded opening 32 designed to receive the threads 28 of the screw portion 26 of the first handle 20.

Handle 30 is fixedly attached to the outer sheath 50 such that rotation of the handle 30 about the longitudinal axis of the device results in corresponding rotation of the outer sheath 50. Handle 30 also preferably includes a release wire actuator 34 attached to the proximal end of a release wire 56 described more completely below. The actuator 34 is preferably mounted for movement along the longitudinal axis of the stent delivery device.

(Gunderson, column 4, line 57 through column 5, line 6).

Gunderson appears to disclose a device including “threads 28 of the screw portion 26 of the first handle 20.” Gunderson appears to disclose a handle 30 “fixedly attached to the outer sheath 50 such that rotation of the handle 30 about the longitudinal axis of the device results in corresponding rotation of the outer sheath 50.” Accordingly, Gunderson appears to disclose a device that is configured to promote (not inhibit) both longitudinal and rotational (e.g., transverse) movement of the components relative to one another. Gunderson does not appear to teach or suggest a combination of features including, but not limited to, the feature of: “one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other.”

In response to similar arguments previously presented, the Office Action states:

Since As seen in Figure 1, Gunderson teaches pins 28, or threading that has protrusions, which promotes movement when rotated, but also inhibits movement, just as a detachable or releasable lock functions. The pins 28 inhibit movement of a first grip 20 coupled to at least a portion of the first conduit relative to a second grip 30 coupled to at least a portion of the second conduit, and therefore Gunderson reads on this limitation.

(Office Action, page 9)

Accordingly, the Office Action appears to take the position that the disclosed threads are analogous to the claimed “pins.” Applicant respectfully disagrees. A “pin” may be defined as “a slender, usually cylindrical piece of wood or metal for holding or fastening parts together, or serving as a support for suspending one thing from another, as: a. A thin rod for securing the ends of fractured bones. b. A peg for fixing the crown to the root of a tooth. c. A cotter pin. d. The part of a key stem entering a lock. e. *Music* One of the pegs securing the strings and regulating their tension on a stringed instrument. f. *Nautical* A belaying pin. g. *Nautical* A thole

pin.” PIN. (n.d.) *The American Heritage® Dictionary of the English Language, Fourth Edition*. (2003). Retrieved September 3 2009 from <http://www.thefreedictionary.com/PIN>. Accordingly, Applicant respectfully submits that the disclosed threads are not analogous to the claimed pin, in combination with other features of the claim.

Accordingly, Applicant respectfully submits that Gunderson does not appear to teach the combination of features in claims 33 and 34. For at least these reasons, Applicant respectfully submits that claims 33 and 34 are allowable over the cited art.

Dependent Claim 53

Claim 53 describes a combination of features including, but not limited to, the feature of: “wherein the first conduit comprises a polymer.” The features of claim 53, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art.

E. The Claims Are Not Obvious Over Heyn In View Of Mikus Pursuant To 35 U.S.C. § 103(a)

Claim 38 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 6,093,194 to Mikus et al. (“Mikus”). For at least reasons similar to those discussed above, Applicant respectfully submits that claim 38 is allowable over the cited art.

F. The Claims Are Not Obvious Over Heyn In View of Quiachon Pursuant To 35 U.S.C. § 103(a)

Claim 52 was rejected under 35 U.S.C. §103(a) as obvious over Heyn in view of U.S. Patent No. 5,938,623 to Quiachon (“Quiachon”). Applicant respectfully disagrees.

The Office Action states:

Heyn discloses the claimed device except for the first conduit comprising a coiled spring.

...

Quiachon teaches a first conduit 42 comprising a coiled spring 61 (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a coiled spring, as taught by Quiachon, to Heyn since it was known in the art that coiled springs used with conduits, sleeves, sheaths or catheters act as dampeners or absorb vibration along the length of a catheter.
(Office Action, page 6)

Applicant respectfully disagrees. Claim 52 describes a combination of features including, but not limited to, the feature of: “wherein the first conduit comprises a coiled spring configured to inhibit collapse of the first conduit.” The features of claim 52, in combination with the features of independent claim 29, respectively, do not appear to be taught or suggested by the prior art. In contrast, the cited portion of Quiachon appear to disclose a coil (61) formed on an outer sleeve 46. *See* Quiachon, col. 5, lines 55-57). Applicant submits Heyn in view of Quiachon does not appear to teach the combination of the features in claim 52. For at least these reasons, Applicant respectfully submits that claim 52 is allowable over the cited art.

G. New Claims

New claim 62 recites: “The stent delivery system of claim 29, wherein the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose a given portion of the stent after all more distal portions of the stent have been exposed.” The cited art does not appear to teach or suggest at least this feature, in combination with the other features of the claim.

New claim 63 recites: “The stent delivery system of claim 29, wherein the second conduit is configured to contain the entirety of the stent between the distal portions of the first and the second conduits.” The cited art does not appear to teach or suggest at least this feature, in combination with the other features of the claim.

New claim 64 recites: “The stent delivery system of claim 56, wherein the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose a given portion of the stent after all more distal portions of the stent have been exposed.”

The cited art does not appear to teach or suggest at least this feature, in combination with the other features of the claim.

New claim 65 recites: "The stent delivery system of claim 56, wherein the second conduit is configured to contain the entirety of the stent between the distal portions of the first and the second conduits." The cited art does not appear to teach or suggest at least this feature, in combination with the other features of the claim.

New claim 66 recites: "The stent delivery system of claim 61, wherein the distal end of the second conduit is movable in a direction toward the proximal end of the first conduit to expose a portion of the stent after all more distal portions of the stent have been exposed." The cited art does not appear to teach or suggest at least this feature, in combination with the other features of the claim.

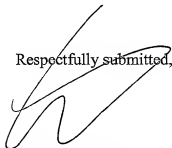
New claim 67 recites: "The stent delivery system of claim 61, wherein the second conduit is configured to contain the entirety of the stent between the distal ends of the first and the second conduits." The cited art does not appear to teach or suggest at least this feature, in combination with the other features of the claim.

H. Additional Comments

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any further fees are required, or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5660-01207/EBM.

Respectfully submitted,



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